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Division of Dockets Management
HFA – 305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Comments to Docket No. 2002N-0278

Dear Sirs:

WAF Customs Brokers has conducted business in the United States since 1978. Serving predominantly the Port of Los Angeles and importers of perishable foods and vegetables, WAF, through its affiliated company, Flegenheimer International, Inc., has been very involved in the ongoing rulemaking implementing the BioTerrorism Preparedness Act of 2002 (the "Act") and continues to be appreciative of the efforts made by the FDA to consider the concerns of the business community. Nevertheless, as demonstrated by the following comments and concerns, the FDA's Prior Notice system, in particular, is not yet in a commercially suitable form and the Agency is urged to delay full enforcement of its implementing rules until a time when such systems are fully functional and transparent.

I. The Ambiguity in the Regulations Create an Unworkable Airfreight Environment

The Prior Notice Interim Final Regulations, in Section 1.278, provides that "A prior notice for an article of food may be submitted by any person with knowledge of the required information. This person is the submitter. The submitter also may use another person to transmit the required information on his/her behalf. The person who transmits the information is the transmitter. The submitter and transmitter may be the same person." While obviously an effort to relieve brokers of the responsibility and liability of having to verify information merely provided to them by their clients, for which the brokers of this firm are grateful, Section 1.278 does not reflect any understanding of the

commercial realities of the global trade environment, particularly in connection with in-bond entries, leading to the very real possibility that no one will timely submit or transmit the Prior Notice despite best efforts to ensure otherwise.

The Interim Final Regulations create a single transmitter of the Prior Notice and one "responsible" submitter of the Prior Notice - a lone entity amongst the distribution chain that is held solely liable for verifying all information required in the Prior Notice. This creates an environment where it is even less likely for a carrier to submit the Prior Notice filing even though the carrier may be the only party uniquely in control of the timeliness of such a filing. For example, in connection specifically with in-bond shipments, Prior Notice must be submitted before the in transit (IT) bond is prepared – the bond may be cut by the steamship line **up to five (5) days before** the vessel arrives at the discharge port but the Prior Notice cannot be filed **more than five (5) days before** the freight arrives at that same port. Therefore, it is critical that, in this case, federal regulation require the Prior Notice be timely submitted by the steamship line; there is no other reasonable manner to ensure compliance with the Act. Insofar as it is unlikely, without regulation, that the steamship lines - or the first airline - will voluntarily prepare and submit the Prior Notice themselves, there is no clear method of ensuring that the filing has occurred or that all downstream imports will not consequently be refused or delayed.

Similarly, a carrier may be transporting cargo loads for numerous "submitters", all of whom are totally unrelated to one another. It is unreasonable for the importer's broker to be contracted to timely transmit the Prior Notice, when that Prior Notice must be filed before arrival at the first port of discharge and the carrier may, without the broker's knowledge, arrive at the first port of discharge weeks before the cargo expected by the broker's client is to arrive at that secondary port of destination. Again, the timeliness of submitting each and every one of the separate Prior Notices related to the cargo being carried by that particular carrier is wholly dependent upon the activities of and only known by the carrier – and there may be very little if anything the submitters or the hired "transmitters" can do to influence such activities.

The Interim Final Regulations that create no particular obligation on any particular party within the distribution system unreasonably holds a single party liable for delays that may arise despite the best of efforts --- including those created by contract --- to ensure that such problems do not arise. While, respectfully, we acknowledge that without a doubt the FDA's Regulations are intentionally drafted to cause an alteration in current business practices, such an effect can only truly occur if the regulations are clear as to what amendments will be necessary of what parties to ensure compliance with the rules. While brokers may be willing to transmit the Prior Notice and their customers may be willing to be identified as the submitter liable for verifying the information contained therein, both of which assumptions of duty will require substantive changes in existing business practices, it is then unreasonable to craft federal regulations that depend upon compliance by third parties over whom neither the transmitter or the submitter have any control or influence. That is, it is simply impossible for the broker to "transmit" the Prior Notice in a timely fashion when, especially in the event of an in-bond or consolidated

shipment transaction, a third party carrier is the only party who will actually know when that clock starts ticking.

Accordingly, for those types of transactions where it is clear that a single, identifiable party within the distribution chain in the sole entity with the ability to timely and/or accurately submit a Prior Notice, the FDA regulations must require that that particular party be so responsible. Although contractual obligations may certainly be negotiated so that entities remain obligated to one another to comply with respective business obligations and in no event would the traders expect or, frankly, desire federal oversight of such private commercial relationships, it is imperative for federal agency regulation to clearly set forth respective responsibilities that are necessary to facilitate --- and not frustrate --- compliance and continuing global business.

II. The Promised "Educational Phase" of Enforcement Never Occurred

Although the FDA published a Compliance Policy Guide promising that "phase 1" of its enforcement of the BioTerrorism regulations would educate importers and brokers about deficiencies in submitted Prior Notices so that such errors could later be corrected, no such education took place and no warnings were received, except in the event no prior notice was filed at all. Accordingly, because the FDA published no indication that such education was *not* taking place, brokers, importers and exporters had every reason to believe that the prior notices they were filing with the FDA from December 12, 2003 through March 12, 2004 were fully compliant and would continue to be accepted by the Agency. In the past few weeks, however, certain colleagues and associates have been receiving "Compliance Audit Letters" effectively putting them on notice of certain errors detected in previously submitted Prior Notices that were never before this month noticed, noted or corrected. As a result, despite business systems already having been changed and clients having been incorrectly advised as to means of compliance, business operations are now again having to endure radical alterations simply as a result of the FDA's apparent inability to timely provide the outreach services promised to the trading community.

The level of frustration escalates because the FDA now publicly proclaims its pending third phase of enforcement during which civil fines may be assessed and increased refusals should be expected. Civil fines and refusals brought about by errors in Prior Notices that, until a few weeks ago, the FDA not only accepted but, by their silence, indicated did not even exist. This type of selective enforcement is undeserved by and unjust to an industry that has already undergone radical and substantial changes in the past year – changes caused not as a result of any terrorism threat discovered in America's food supply but merely because the FDA elected to implement relatively business-friendly legislation in a markedly unfriendly and controversial manner. The FDA must be cognizant of this failure in promised transitory enforcement and must alert the trading community to delayed full enforcement of these regulations until more thorough outreach and education is completed.

III. Full Enforcement Must Be Delayed

As indicated herein, there remains substantial confusion and concern regarding the Interim Final Regulations. Although FDA's continued outreach and additional efforts are commendable, they have not sufficiently trained the trading community nor have they been adequately responsive to the needs of this critical industry. Because the first phase of enforcement never occurred and, as a result, brokers and importers have been operating under perhaps an erroneous belief that full compliance has occurred, the FDA must delay full enforcement until such a time that the FDA systems are fully operational and adequate training has been completed.

In addition, there is no question that most of the Airlines Cargo Terminals are not equipped with sufficient general order warehouses to store the "refused" merchandise that should be anticipated if the FDA intends to strictly apply its published compliance schedule. And, if the FDA does not intend to strictly apply such a standard, then any attempt at arbitrary enforcement must similarly be outrightly rejected because non-compliance with the Interim Final Regulations is not a subjective but a very technical and objective standard that cannot be and must not be only sometimes applied. As a result, then, of the need to strictly apply the regulations when and if they are to be applied at all, the FDA must put into place the tools it needs to perform the enforcement duties it assumes. And, to reiterate, there are not a sufficient number of general order warehouses to store the food articles that will necessarily need to be refused for non-compliance with these regulations. By the FDA's own estimates, only half – if that many – of the facilities required to be registered with the Agency have in fact been registered and nearly half of all prior notices presently being received are incomplete or inaccurate. As a result, then, nearly half of all imported food products currently entering the U.S. will need to be stored at least temporarily in general order warehouses because they will be refused entry under these Interim Final Regulations that provide no flexible means for determining compliance (such as dialog with the importer, exchange of additional or alternative documentation, etc.). To enforce regulations as of August 13, 2004 when the Agency has undertaken no obvious measures to equip U.S. ports with the means to store or hold especially the perishable goods that will, as of that date, not be able to move except to a general order warehouse, is to intentionally and with malfeasance disrupt legitimate and critical global trade in food products that may pose absolutely no threat to the health or safety of any U.S. consumer.

The FDA must delay full enforcement --- with notice to the trading community of such delay – until it has done all that is necessary to equip the U.S. ports to handle refused perishable goods. In addition, the FDA must, during such a delay, continue its outreach to the trading community including, without limitation, extending any comment period in order to better assess the impact of the Prior Notice regulations upon impacted industries. While brokers and importers are still being training on the software intended to facilitate compliance with the Prior Notice systems, because those systems are still experiencing periods during which they are not fully operational, because the FDA itself was unable to properly educate the business community about these regulations and because U.S. ports are not equipped to properly store all of the refused products that will necessarily need to

be held at the ports once these regulations are fully enforced, it is critical that the Agency immediately publish a notice that full enforcement of the regulations will be delayed until a final rule is promulgated and all comments ---- even those received thus far --- are more fully and fairly considered.

Conclusion

Flegenheimer International appreciates the FDA's continuing efforts to learn the trading community's experience with the Prior Notice regulations prior to full enforcement of these rules. In that regard, it is sincerely hoped that the comments submitted in this communication be considered carefully and thoughtfully. There is no question but that the Agency must delay enforcement of these regulations until it has finalized its regulations, more thoroughly perfected its systems, properly prepared our ports and educated the business community.

The undersigned would be very appreciative of the opportunity to discuss these comments with the FDA in person and via a continuing dialogue. Please feel free to contact me directly at any time.

Respectfully submitted,
Flegenheimer International

By: _____
William Flegenheimer
President